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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,023	02/09/2001	Neil H. Riordan	RIORD.006A	1580

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EXAMINER

DAVIS, NATALIE A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/11/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/781,023

Applicant(s)

RIORDAN, NEIL H.

Examiner

Natalie A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 and 70-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 and 70-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Applicant's election without traverse of Group II, claims 28-34 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 28-34 are being examined as belonging to the elected Group II, while claims 1-27 and 35-48 are withdrawn from examination as being drawn to a non-elected invention.

Applicant's amendment filed 24 January 2002 (Paper No: 6) is acknowledged.

Accordingly, claims 36-69 are cancelled and claims 70-79 are new. Claims ~~36-69~~ and ~~79-79~~ are under examination. 70

Information Disclosure Statement

The information disclosure statement has been considered. A signed copy is attached hereto.

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 18-19 and 33-34 are drawn to the method of claims 1 or 20 further comprising administering an effective amount of an immune-stimulating compound such as adjuvant, heat shock protein, or bacterial cell wall extract. However, the specification does not teach, guide, or make any mention of using adjuvant, heat shock protein, or bacterial cell wall extract in the method as claimed. Accordingly, the specification does not provide any antecedent basis for the subject matter claimed.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-19 and 70-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rote, et al., (1980) in view of Murphy, et al. (1996) and Nestle, et al. (1998), Ravery (1999), Morales, et al. (1995), and Yedavelli, et al., (1999).

4. Rote, et al. teach the presence and isolation of tumor-associated antigens (urine isolates) in the urine of cancer patients (abstract). The urine isolates were concentrated using a 10,000 molecular weight exclusion filter. Rote does not teach a method of treating cancer using the urine isolates. However, Murphy, et al. teach the potential of using dendritic cells (antigen presenting cells-APC) pulsed with prostate specific membrane antigen (PSMA) (tumor antigens) in the treatment of prostate cancer (abstract) and Nestle, et al. teach the use of dendritic cells for tumor antigen delivery in the treatment of cancer (p. 328). Ravery, teach the presence of PSA in the urine of patients with prostate cancer. Yedavelli, et al., teach the use of a heat shock protein in the treatment of cancer and Morales, et al, teach the use of bacterial cell wall in the treatment of tumors. It would have been obvious at the time of the invention to one of ordinary skill in the art to use tumor-antigen derived from urine (urine isolate) in the treatment of cancer since Murphy and Nestle teach the treatment of cancer using tumor antigens and Rote teach the presence of tumor associated antigens in the urine of cancer patients, but not in the urine of normal patients. Likewise, since Ravery teach the presence of PSA in the urine of patients with prostate cancer and Murphy teach treatment of prostate cancer with dendritic cells pulsed with PSMA, one would be motivated to use urine isolates in the treatment of cancer. One of ordinary skill in the art would be motivated to use DC pulsed with urine isolates since Nestle indicate the vaccination of autologous DC pulsed with tumor antigens in the treatment of melanoma and teach the capacity of DC's for induction of an antitumor-specific immune response (p. 328). It would be obvious to use urine isolates of various sizes since Rote teach molecules greater than 1,000,000 daltons may be dissociated into smaller active fragments by treatment with 6M urea. Furthermore, one would be motivated to administer the isolate as claimed as taught by Murphy and use exosomes since they are derived from APC. Furthermore, one of ordinary skill in the art would know how much urine to collect for filtering and

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concentrating and to use a concentrator equipped with a 1000 dalton filter in order to isolate molecules larger than 1000 daltons.

5. In view of In re Kerkhoven, 205 USPQ 1069 (CCPA 1980), wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to for a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. It would have been obvious to one of ordinary skill in the art to use an immune-stimulating compound such as a heat shock protein or bacterial cell wall extract in the method as claimed, since Morales and Yedavelli teach their use in the treatment of cancer.

6. Claims 20-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rote, et al., (1980), Murphy, et al. (1996), Nestle, et al. (1998) Morales, et al. (1995), and Yedavelli, et al., (1999) as applied to claims 1-19 and 70-79 above, and further in view of Cariuk, et al., (1997).


7. Cariuk, et al., teach the presence and isolation of a 24,000 molecular weight antigen from the urine of cachectic patients (abstract). Since Cariuk teach an antigen present in the urine of patients with cachexia due to cancer or other diseases, one would be motivated to use this urine isolate in the treatment of cachexia in view of the above teaching.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie Davis, PhD
April 8, 2002


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